WASHINGTON LEGAL FOUNDATION
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WASHINGTON, D. C. 20036
202 588-0302

December 8, 1999

Petitions Control Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments in Support of the Food Irradiation Coalition Petition for Rulemaking Regarding Food Irradiation

Dear Sir or Madam:

The Washington Legal Foundation (WLF), in conjunction with the Public Interest Litigation Clinic of the George Mason University School of Law, hereby submits these comments in support of the petition submitted on August 23, 1999, by the Food Irradiation Coalition (FIC) led by the National Food Processors Association and endorsed by approximately thirty other groups, including educational institutions such as Kansas State University, and consumer groups such as Consumer Alert. The petition seeks to have the Food and Drug Administration (FDA) approve the greater use of food irradiation for various ready-to-eat foods, including meat and poultry, and fruits and vegetables.

Interests of WLF

WLF is a non-profit, public interest law and policy center, based in Washington, D.C., with supporters nationwide. WLF promotes limited government regulation, free market solutions to societal problems, and economic freedom. In particular, WLF devotes substantial resources to opposing excessive FDA regulation that is detrimental to health care in America and violative of constitutional rights. For example, WLF successfully sued the FDA under the First Amendment over the FDA's off-label use policy that prohibited the dissemination to doctors of certain articles and journals that described the beneficial uses of FDA-approved drugs and devices for off-label use. See *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999). Of particular relevance to the issue of food irradiation, WLF submitted comments on July 19, 1999, to the FDA responding to the FDA's Advanced Notice of Proposed Rulemaking on the Labeling of Foods Treated with Ionizing Radiation, Dkt. No. 98-N-1034, 64 Fed. Reg. 7834 (Feb. 17, 1999).

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Introduction and Summary

WLF supports the FIC petition because it promotes the public interest in the following ways:

(1) The use of food irradiation for frozen, refrigerated, and dried food products allows for lower costs in food production and consequently, benefits individuals and families living at or below the poverty line;

(2) Irradiated food has a longer shelf life and may be exported to third-world countries in remote regions where food is scarce;

(3) The World Health Organization (WHO) along with forty-four countries endorse and currently use food irradiation without any known problems; and

(4) Food irradiation allows for the decreased use of pesticides and herbicides that may have adverse environmental effects.

1. Food Irradiation Is Beneficial to Low-Income Individuals and Families.

The use of food irradiation is less costly than the use of chemical preservation and refrigeration; hence, food processors and retail grocery stores are able to sell meat and vegetables at lower prices than non-irradiated food. The lower cost associated with food irradiation would enable low income families who would not usually be able to purchase nutritious food to afford to buy these foods for their children. As a result, many developmental delays that have been associated with poor nutrition in children living in poverty may be alleviated. The ultimate societal gains from having children that have increased mental and physical development as a result of having the proper nutrition at an early age has yet to be determined, but could ultimately lead to a more productive society and economy.

The minute loss of a few vitamins from foods that are irradiated is no greater and no more severe than the loss that would be expected from foods that are cooked either conventionally or in a microwave. The over-all benefits from the total protein and vitamin content that low income families gain from being able to afford such foods significantly outweighs by any slight loss in vitamins.

The negative backlash and unjustified fear of food irradiation that has been spread by so-called "public interest" groups may actually harm low income families more than help them. Because low income families may not have adequate cooking facilities to prepare or store their food, or have insufficient information about the microbial dangers associated with under-cooked beef and poultry, they will be at a greater risk for food poisoning -- a risk that could be significantly reduced if food irradiation were more available.

Legislators are wary about supporting measures that have been labeled as "harmful" by activist public interest groups. Dale Blumenthal, Toxic to Bacteria, Safe to Humans, FDA Consumer (Nov. 1990) (hereinafter "Blumenthal"). As a result, agencies such as the FDA must carry out their duties to support a scientifically legitimate form of pathogen control in foods in order to meet the needs of all members of society. The FDA should be skeptical of arguments from "environmentalists" who claim to support the public interest, but seem to have forgotten about America's low income families. But even a few public interest groups have now become somewhat more tolerant of the concept of food irradiation, although they have recommended that at a minimum, irradiated foods should be labeled. Blumenthal at 3. However, as expressed in WLF's comments submitted earlier to the FDA on the subject, any such labeling should not be required to convey a "warning" message when, in fact, there is no health dangers associated with irradiated foods.

2. Foods Irradiated In America Significantly Benefit Other Countries.

Many foreign countries are dependent upon American grain and meat products for their food supply. Food irradiation enables American food producers to compete better in foreign markets that would not normally be available to American products. In addition, due to the limited availability of refrigeration in many third-world countries, the use of food irradiation can allow for shipment of meat and other easily spoiled food products to remote regions. Because of the lower costs, many low income countries can afford to purchase and feed their populations with American food products. As a result, many new markets that were previously closed to American markets because of high costs required for processing prior to shipment will now be open. The United States will be able to develop new ties and strengthen existing relations with countries by feeding a larger percentage of the third world population.

Countries that have shunned American products in the past as being unsafe, such as France, are now using irradiation to treat their own food products. While there has been some international concern over accidents at certain nuclear energy facilities, the use of Cobalt 60 and Cesium 137 in food irradiation does not create any by-product in the form of spent fuel rods or radioactive sludge that would require disposal. In fact, simple electron rays or X-rays, similar to those used in a dental office, may be used in food irradiation. The International Committee on the Wholesomeness of Irradiated Food, comprised of the World Health Organization, the International Atomic Energy Agency, and the United Nations, has maintained since 1980 that food irradiation up to 10 kiloGrays does not cause any toxicological effects in humans, and introduces no special nutritional or microbiological problems. Blumenthal at 5.

3. The World Health Organization Currently Supports the Use of Food Irradiation Throughout the World.

The World Health Organization (WHO) has maintained that "access to nutritionally adequate and safe food is a right of each individual". FAO/ WHO International Conference on Nutrition (ICN), Rome 1992. The WHO has formed the International Consortium Group on Food Irradiation (ICGFI) with forty-four current member nations for the specific purpose of expanding international use of food irradiation. Since ICGFI's establishment in 1983, European countries which have traditionally been considered highly conservative with regards to pesticide/herbicide use on their food products, and at various times have banned American foods such as beef, have adopted ICGFI's policy of across the board use of food irradiation. These countries include France, Germany, United Kingdom, and Canada. Recently, ICGFI published two major reports advocating the benefits of food irradiation for fruits and vegetables in further support of its previous position favoring food irradiation on meat and poultry products. Finally, a recent international conference held in Sydney and Melbourne, Australia in September 1999 promoted the international advancement of food irradiation by ICGFI countries.

4. Food Irradiation Allows for a More Environmentally-Friendly Use of Food Processing and Production.

The use of chemicals in food processing has been criticized by "health advocates" because of the purported harmful effects from the consumption of these additives. In fact, the Delaney Clause of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §348(c)(3), forbids the addition of carcinogenic substances to foods. Because food irradiation adds no chemicals to the content of foods, the food is considered "pure" because it has not been altered through the use of additives or preservatives to prevent the spread the growth of microbial pathogens. As a result of less reliance on chemicals by food processors, the environmental clean-up and pollution control costs to the federal and state governments will also decrease as the use of food irradiation increases.

The use of Cobalt 60 has no significant environmental or nutritional side effects because food irradiation adds no chemicals to the contents of foods. Other methods of food irradiation, such as ionization or electron beam, also have no known side effects nor add any chemical substance to the contents of foods. In fact, food irradiation may help prevent certain pathogens that have caused some serious problems such as Escherichera coli (E. coli). This pathogen has been found in some ground beef and forces many restaurants and consumers to over-cook their beef before consumption. The Mayo Clinic has recommended the use of food irradiation as a way to reduce substantially the presence of E. coli in beef. Thus, many unnecessary hospitalizations and deaths, particularly of infants or immuno-compromised individuals, can be prevented. Nine thousand Americans die annually from food poisoning. Michael Fumento, The Wages of

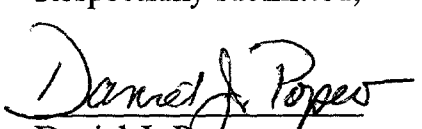
Food Irradiation Delay Decades of Death 1, American Enterprise Institute. The use of food irradiation can help stop the three biggest killers: campylobacter, salmonella, and E. coli. Id.

In addition to the World Health Organization, the American Gastroenterological Association and the United Nations Food and Agricultural Organization have also recommended the use of food irradiation. According to Fumento, the fact that only six food processors in the field of food irradiation have been injured in the last forty years is greatly outweighed by the number of lives that would be saved every year from food poisoning, not to mention the reduced costs to individuals and the government due to less hospitalizations and medical treatment. The acting director of microbiology at the FDA has stated that 60 percent of poultry sold in the United States has Salmonella and virtually all poultry has the Campylobacter bacteria. Blumenthal at 5. With such high rates of microbiological toxicity present, food irradiation becomes a low-risk, effective tool in the preservation of American and international health.

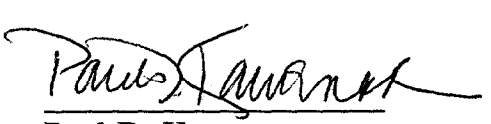
Conclusion

Based on the foregoing reasons, WLF submits that the expanded use of food irradiation as proposed in the petition submitted by the Food Irradiation Coalition would be in the public interest and benefit every American by promoting a safer and healthier society.

Respectfully submitted,



Daniel J. Popeo
General Counsel



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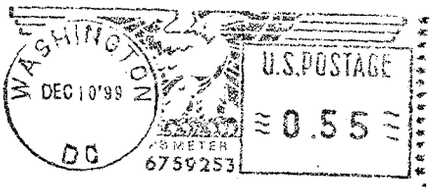
* These comments should not be construed to imply institutional endorsement by George Mason University or its School of Law.



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